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0801 8 FEB 11 A627

February 8, 2008

BY FAX

Division of Dockets Management (HFA-305)

Food and Drug Administration

5630 Fisher Lane Rm 1061

College Park, MD 20852

Re: Docket No. 2007D-0491: Draft Guidance Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (December, 2007)

Dear Sir or Madam:

On behalf of our clients, we appreciate this opportunity to provide comments to the above-referenced draft guidance which was announced in the Federal Register on January 2, 2008.

CFSAN's Guidance

1. **What information must be included on the label of a dietary supplement to enable consumers to report serious adverse events associated with the use of the dietary supplement?**

Section 403(y) of the FFD&C Act (21 U.S.C. 343(y)) requires the label of a dietary supplement being marketed in the United States to include "a domestic address or domestic phone number through which the responsible person ... may receive a report of a serious adverse event with such dietary supplement." If the label does not include the required domestic address or phone number, the dietary supplement is misbranded.

When the responsible person chooses to provide a domestic address (rather than a phone number) for adverse event reporting, FDA concludes that the statute requires the product label to bear a full U.S. mailing address that includes the

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street address or P.O. box, city, state, and zip code of the responsible person (i.e., the manufacturer, packer, distributor, or retailer identified on the dietary supplement label). FDA finds that Congress's use of the term "domestic address" in section 403(y) is a clear and unambiguous directive that dietary supplement labels include all information necessary to enable a serious adverse event report to reach the responsible person. This reading of section 403(y) is supported by dictionary definitions of "address," which include "the indication of destination, as on mail or parcels" and "the location at which a person or an organization may be reached" (Ref. 1). Indeed, an address does not serve its intended purpose unless it includes all the information necessary to enable mail to reach its destination.

Similarly, when the responsible person chooses to provide a domestic phone number for adverse event reporting, FDA concludes that the statute requires the phone number on the product label to include the area code. Without the area code, the phone number is incomplete and does not serve its intended purpose of enabling the consumer to contact the responsible person to report a serious adverse event.

Congress's use of the phrase "through which the responsible person ... may receive a report" to modify "domestic address or domestic phone number" further supports FDA's conclusion that a complete address or phone number must be provided. This phrase shows Congress's intent that the domestic address or phone number on the label be sufficient to ensure that the responsible person will actually receive the serious adverse event reports that consumers submit. If the address provided on the product label for adverse event reporting is incomplete (e.g., no street address or P.O. Box), some of the serious adverse event reports that are submitted to the responsible person by mail likely will not be received. In addition, when consumers notice the incomplete address, they may decide not to submit a report to the responsible person because they believe it will not be received. Similarly, a phone number without an area code would be useless to consumers except for those who happen to be in the same area code as the responsible person.

The use of the term "domestic address" in section 403(y) contrasts with Congress's use of a different term, "place of business," in section 403(e) of the FFD&C Act (21 U.S.C. 343(e)). Section 403(e) provides that foods, including dietary supplements, are misbranded unless the product label bears the name and place of business of the manufacturer, packer, or distributor of the food.

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FDA's regulations interpret "place of business" to require only the firm's city, state, and zip code to appear on the product label, as long as the firm's street address is listed in a current telephone directory or other city directory (21 C.F.R. 101.5(d)). The use of the term "domestic address" in section 403(y) demonstrates Congress's intent to require the responsible person's full address, including the street address or P.O. Box, to appear on dietary supplement labels when the responsible person has opted to receive serious adverse event reports by mail. If Congress had considered the less complete address already required under the "place of business" labeling regulation to be adequate for serious adverse event reporting, there would have been no need to impose a new, more specific requirement in section 403(y) for the responsible person's "domestic address" to appear on dietary supplement labels.

Our Response:

CFSAN's argument that a "domestic address" and "place of business" are two different requirements is both irrational and inconsistent with current FDA regulations. Further, there is no basis to conclude that Congress intended to impose a new requirement with this language. Instead, the obvious intent was to specify that the address needs to be "domestic" (as opposed to outside of the U.S.). Therefore, the "place of business" as defined in current labeling requirements is sufficient as long as it is "domestic." A current FDA regulation, 21 C.F.R. § 101.5(d), establishes the agency position that meeting the "place of business" requirement provides sufficient information to allow any interested parties, including consumers, to contact any company identified as this regulation specifies. For FDA to now argue that this information is not sufficient is irrational and contrary to long-held FDA practice and continuing agency regulatory requirements and policy. Whether or not a P.O. Box is included or an actual street address is not the relevant issue – the issue is whether the label includes sufficient information for consumers to be able to find the complete address and contact the company should they wish to file a report. FDA's established position is that meeting the "place of business" requirement is sufficient to permit consumer contact. Therefore, there is no basis for requiring additional information on already – crowded labels, and FDA's draft guidance on this issue must be withdrawn.

- 2. Should the label of a dietary supplement also include language indicating that the purpose of the domestic address or phone number is to report serious adverse events associated with use of the dietary supplement?**

Although section 403(y) does not require a dietary supplement label to include anything other than a domestic address or phone number for the responsible

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person, FDA recommends that the label also bear a clear, prominent statement informing consumers that the domestic address or phone number is for reporting serious adverse events associated with use of the product.

FDA would have no objection to a firm's combining the recommended statement with language informing consumers that the domestic address or phone number on the label may also be used for other purposes, as long as the information provided is not false or misleading. For example, a dual-purpose label statement might be "To report a serious adverse event or obtain product information, contact..." or other similar language.

Our Response:

The Senate Committee on Health, Education, Labor and Pensions considered this exact issue and stated, as FDA's draft guidance appears to recognize that "[t]he legislation does not require the label to make any statement other than providing the address or phone number." S. Rep. No. 109-324, at 9 (2006). The recommendation in FDA's draft guidance will be misunderstood by many readers as a "requirement." Therefore, FDA should add a clarifying sentence at the end of this section as follows: "The inclusion of any statement is entirely optional and FDA will take no action to require such a statement."

3. When do the labeling requirements in section 403(y) become effective?

Under section 3(d)(2) of the Dietary Supplement and Nonprescription Drug Consumer Protection Act, the labeling requirements of section 403(y) of the FFD&C Act apply to all dietary supplements labeled on or after December 22, 2007. Therefore, these labeling requirements are already in effect. However, FDA intends to exercise enforcement discretion for the new labeling requirements until January 1, 2009.

Congress provided one year after the Dietary Supplement and Nonprescription Drug Consumer Protection Act was signed into law on December 22, 2006, for affected firms to comply with its new requirements. However, due to competing priorities, FDA was not able to consider and develop guidance on the labeling requirements of Section 403(y) within this time period. As a result, firms did not have the benefit of FDA's guidance on how to comply with the new labeling requirements when the requirements went into effect. Therefore, we find that it is reasonable to allow an additional one-year period for firms whose dietary supplement labels do not yet meet the requirements of section 403(y) to bring their labeling into full compliance. This period of enforcement discretion,

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consistent with the initial length of time for compliance provided for in the law, should be adequate to enable all firms to meet the new labeling requirements for dietary supplements. FDA intends to begin enforcing the requirements of 403(y) for dietary supplements labeled on or after January 1, 2009.

Our Response:

No comment.

We urge you to amend the draft guidance to address these issues.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'A. Wes Siegner, Jr.', is positioned above the printed name.

A. Wes Siegner, Jr.

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